CASE REPORTS

The utility of commercially available endografts in the treatment of contained ruptured abdominal aortic aneurysm with hemodynamic stability

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Purpose: **Food and Drug Administration–approved endografts are suitable for the elective repair of abdominal aortic aneurysms (AAAs) with favorable aneurysm anatomy. Our aim is to illustrate the feasibility and versatility of commercially available endografts for emergency AAA repair in hemodynamically stable AAA rupture.**
Methods: **From June 2001 to July 2002, five patients presented with severe abdominal pain and were diagnosed with contained rupture of an infrarenal AAA. In all cases, patients were deemed unfit to withstand conventional open repair by both the referring outside medical center as well as our center's team. All patients were hemodynamically stable on arrival at our medical center. Measurement and selection of endovascular devices were based on computed tomography (CT) scans performed emergently at the outside referring center. The required emergently procured endografts were obtained within 2 to 4.5 hours (mean, 3.1 hours) of presentation. Complex anatomy at the proximal and distal fixation zones or difficult access was present in every case.**
Results: **All patients survived endograft repair and had successful exclusion of their aneurysm sac on the basis of intraoperative arteriography and postoperative CT surveillance. All were discharged to home at baseline function within a mean of 6.8 days (range, 2-13 days). There were no deaths. There was one postoperative pulmonary embolism, one myocardial infarct, and one type 2 endoleak. Mean operative time and blood loss were 4.67 hours and 217 mL, respectively. At a mean follow-up of 18 months, CT scans showed stable or shrinking aneurysm sacs.**
Conclusions: **In patients with contained ruptured AAAs who present with hemodynamic stability and comorbidities that preclude open surgery, commercially available endografts are a versatile treatment option even in the face of complicated aneurysm anatomy. (J Vasc Surg 2004;40:154-60.)**

During the last 10 years with the introduction of endovascular technology, elective abdominal aortic aneurysm (AAA) repair evolved to a minimally invasive approach. Emergency presentations, however, continue to be mostly treated by standard open repair. Although some authors remain skeptical regarding the long-term results of endovascular AAA exclusion,[1,2] endovascular repair has been reported to have improved postoperative morbidity and mortality.[3,4]

Emergency open AAA repair for rupture is associated with high morbidity and mortality. The utility of the endovascular approach for emergency AAA presentations has been explored at a limited number of centers, usually with surgeon-made endografts. Usually the conditions of urgent aneurysm repair preclude the required detailed imaging and measurements for endograft design. In addition, commercial procurement of the designed endograft might take too long to meet the needs of an emergency AAA presentation. These devices are extremely costly and are not supplied by consignment; therefore most centers do not carry "on-the-shelf" inventory in their operating rooms. Some groups have introduced their own "one-size-fits-most" custom-made endograft design for ruptured AAAs with great promise.[5,6] However, the majority of vascular surgeons have access only to the commercially available devices approved by the Food and Drug Administration (FDA). In the setting of an emergency presentation, the time needed for endograft design and procurement would deter most vascular surgeons from entertaining the endovascular approach as a treatment option.

We report a group of 5 patients with contained ruptured AAAs who were transferred to our medical center from neighboring centers because their medical comorbidity placed them at prohibitive morbidity/mortality rate with open AAA repair. On medical assessment by our team and concurrence that medical comorbidities were prohibi-

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Table I. Summary of key pre-existing severe advanced comorbidities in patients treated and blood pressure on initial presentation

Patient A	*Patient B*	*Patient C*	*Patient D*	*Patient E*
S/P MI (2 wk prior)	COPD*	COPD*	NSC lung carcinoma	Ongoing MI
PBP, 118/62 mm Hg	PBP, 134/76 mm Hg	PBP, 110/57 mm Hg	PBP, 133/70 mm Hg	PBP, 142/68 mm Hg
CAD†	CAD	Disabling DJD	Brain metastases‡	CAD†
S/P CVA	CHF§	Carotid stenosis		COPD
Severe aortic stenosis	IDDM			
PAD	Renal insufficiency			
Renal insufficiency				

PBP, Presenting blood pressure; *MI,* myocardial infarct; *COPD,* chronic obstructive pulmonary disease; *DJD,* degenerative joint disease; *NSC,* non–small cell; *CVA,* cerebrovascular accident; *IDDM,* insulin-dependent diabetes mellitus; *PAD,* peripheral arterial disease; CAD, coronary artery disease; *CHF,* congestive heart failure; *S/P,* status post.
*Oxygen-dependent at home.
†Non revascularizable unstable angina.
‡S/P irradiation treatment.
§Myocardial injection fraction < 15%.

tive of the open approach, these patients were treated with FDA-approved endografts. These patients were all hemodynamically stable on arrival at our medical center. In these emergency settings, available imaging was usually less than optimal, including noncontrast computed tomography (CT) scans or thick-cut CT scans. However, although commercially available endografts are certainly not "one-size-fits-all," these devices proved to be sufficiently versatile to allow successful AAA exclusion in these emergency presentations.

PATIENTS AND METHODS

From June 2001 to July 2003, 10 patients presented with ruptured AAAs. Five of these patients presented to outside medical centers with abdominal pain and were found to have infrarenal AAA rupture by emergency department CT scans. All 5 patients were transferred to our medical center for a second opinion, because open repair was thought to be of prohibitive risk because of associated medical comorbidities. They were all hemodynamically stable. Three of the 5 patients had been diagnosed with AAA >5 cm before presentation, 2 of whom had prohibitive medical conditions for open repair, and the third patient was in the midst of a cardiac evaluation expected to yield evidence of prohibitive risk because of new-onset unstable angina. The remaining 2 patients were first diagnosed with AAA at the time of their rupture by CT scan in the emergency department. Table I summarizes the pre-existing medical comorbidities of all cases.

Endografts were expeditiously procured with any available imaging. The focus of the design was to determine the outer-to-outer width of the aorta at the level of the renal arteries and the outer-to-outer diameter of the distal left and right common iliac arteries. As best as possible, the extent of the aneurysm, calcification, and angulation were estimated, and they influenced the endograft design. However, multiple potential designs were formulated in a plan A, B, and C fashion.

The endografts were procured from both Guidant (ANCURE; Indianapolis, Ind) and Medtronics (AneuRx; Minneapolis, Minn). Clinical specialists from the respective companies were contacted, and all components of the potential designs were urgently requested. On the basis of availability and estimated time of arrival, the operating room was instructed to reserve a room in anticipation of an endograft repair of a ruptured AAA. All patients were informed of the uncertain nature of these procedures in the acute setting and that waiting could prove fatal. However, they were also informed that the likelihood of surviving an open repair was very low, a medical assessment that had also been given by an independent medical team before their transfer to our medical center. One patient, who waited 24 hours for his repair, had family who were ambivalent about providing further medical care, hence the delay in surgery. This patient was admitted to a regular floor bed with a do-not-resuscitate status. The remaining patients were all sent to the preoperative holding area, in which they received critical care from attending anesthesiologists, surgeons, and nursing. Patients were treated with intravenous fluids, Foley catheters were placed, and blood pressure was controlled with intravenous nitroglycerin for systolic blood pressure of 80 to 100 mm Hg.

The usual instrument sets used for open repair and endovascular repair were made available on the sterile field. Imaging was performed with the OEC 9800 mobile C-arm. Patients were brought to the operating room within 1 hour of the anticipated arrival of the endograft. Frequent communication with the clinical specialists facilitated time estimation.

Patients were prepped from the upper chest to the knees and draped before induction of general anesthesia. Patient B underwent local anesthesia with sedation, whereas the other patients underwent general anesthesia. Arteriography was first performed via left or right groin puncture to delineate current anatomy and feasibility of endograft deployment. This intraoperative imaging study

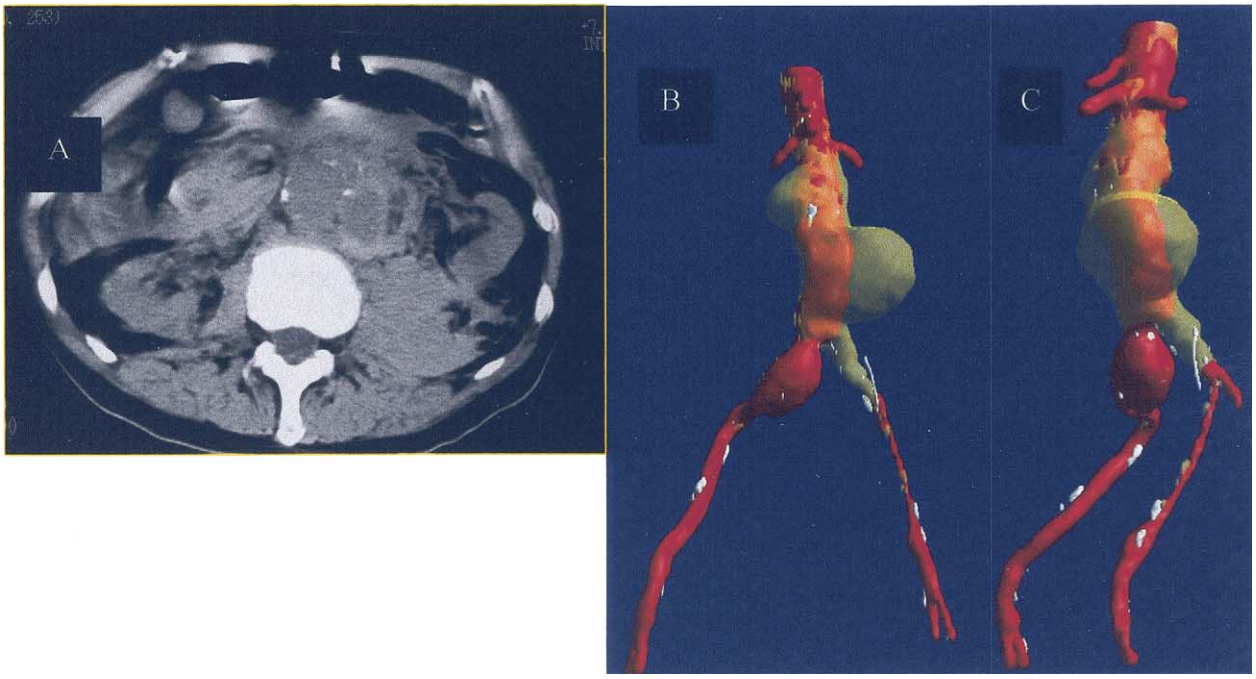

Fig 1. A, CT scan of ruptured AAA in patient B. **B** and **C,** Retrospective three-dimensional reconstructions of CT data from AAA in patient B. Left common iliac artery and right hypogastric artery occlusion are noted.

Table II. Summary of key aortoiliac dimensions/features with focus on fixation zones

Anatomic factor	*Patient A*	*Patient B*	*Patient C*	*Patient D*	*Patient E*
Infrarenal neck diameter (mm)	25	25	23	26	25
Infrarenal neck length (mm)	12	21	38	20	15 (left renal)
AAA maximum diameter (mm)	85	60	60	57	62
Distal right CIA diameter (mm)	10	25 (EIA, 10 mm)	13	15	15
Distal left CIA diameter (mm)	8	Occluded	14	13	15
Right CIA calcification	Moderate	No (aneurysmal)	No	Mild	No
Left CIA calcification	No	No (occluded)	No	Mild	No
Patency of hypogastric arteries	Patent	Right, occluded; left, patent	Patent	Patent	Patent

CIA, Common iliac artery; *EIA,* external iliac artery.

was compared to the available imaging to confirm that there were no gross anatomic contraindications to endovascular repair. A cutdown on both common femoral arteries was made. A standard sequence (the same as for elective cases) was followed for each endograft deployment. We used full heparinization (100 U/kg) for these procedures as close to deployment of the endograft as possible. Table II summarizes the key anatomic measurements with focus on endograft fixation zones. Details of the utilized devices and design descriptions for each patient are listed in Table III.

Patient B had particularly complex aneurysm anatomy from the perspective of attempting endovascular treatment (Figs 1 and 2). The left common iliac artery was chronically occluded, and the right common iliac artery was aneurysmal. The left common iliac occlusion warranted a planned conversion to an aorto–right uniiliac design. When using the AneuRx device, this can be accomplished by occluding the flow divider with the use of a proximal aortic cuff. Because of the presence of an aneurysmal right common iliac artery, distal fixation required deployment of an iliac limb extension landing distally in the right external iliac artery. The right hypogastric artery was chronically occluded at baseline. A right to left femoral-femoral bypass was then constructed to provide contralateral limb perfusion as well as retrograde perfusion to the pelvis via the left hypogastric artery. A contralateral occluder for the left common iliac artery was not used because we relied on the chronic occlusion as a means of protection from retrograde flow into the sac. Chronic calcified occlusive disease (unlike acute soft thrombus) at the left common iliac artery obliterated the lumen of the artery. This situation was thought to be protective against retrograde aneurysm sac pressurization.

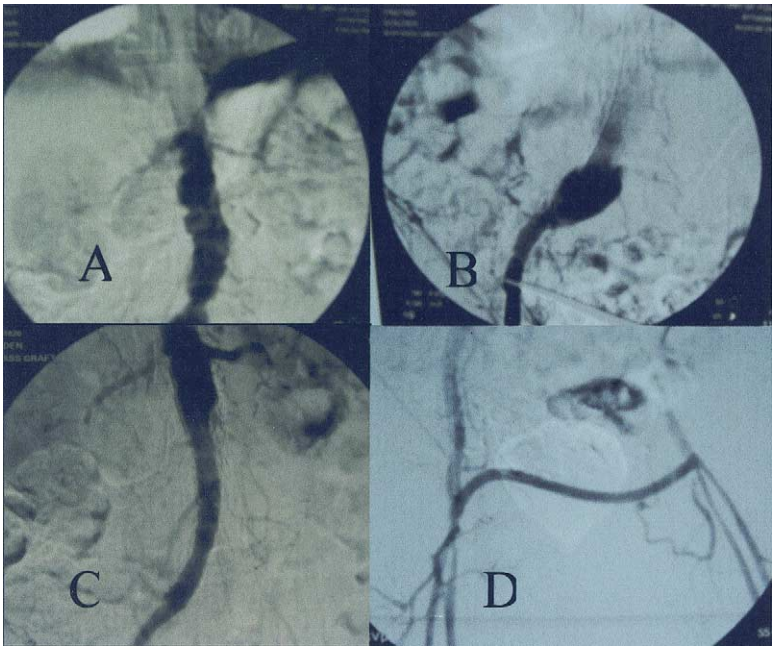

Fig 2. Intraoperative arteriograms of patient B. **A,** Initial arteriogram demonstrating left common iliac occlusion and a right common iliac aneurysm. **B,** Initial deployment of the graft body and retrograde injection of the right iliac system. **C,** Conversion to an aorto–uni-iliac system with the use of an aortic extension cuff across the flow divider. **D,** Completion arteriogram after femoral-femoral bypass with 8-mm polytetrafluoroethylene.

Table III. Summary of endograft make and design used for AAA endovascular exclusion

Graft-anatomy	*Patient A*	*Patient B*	*Patient C*	*Patient D*	*Patient E*
Endograft type	Ancure	AneuRx	AneuRx	AneuRx	AneuRx
Main body	26 × 13	28 × 16*	26 × 15	28 × 16	28 × 16
Iliac extensions	Stenotic common iliacs	16 × 11.5	15 × 11.5	16 × 11.5	16 × 11.5
Delivery sheath size	25 French	21 French	21 French	21 French	21 French

*Modular bifurcated main body was converted to aorto–uni-iliac design by deployment of a proximal aortic extension cuff (28 × 3.75) to occlude the flow divider.

Patient E presented with abdominal pain and syncope. A noncontrast CT scan showed the ruptured AAA. The patient was transported by helicopter to our facility. The cross-sectional dimensions of the proximal and distal fixation zones were relayed by phone from the outside medical center's radiologist to our vascular surgeon. An endograft representative was immediately contacted, and the required endovascular components were ordered. Both patient and graft arrived simultaneously 2 hours later, and at that time the patient was hemodynamically stable but had marked ST segment elevations and tachycardia. After general anesthesia was induced, an arteriogram was obtained, and the neck length of the aneurysm measured approximately 15 mm below the left renal artery but was angulated and ulcerated, with the aneurysm extending to the level of the right renal artery. After deployment of the endograft, a large type I endoleak was evident at the right renal artery. This was repaired with a proximal extension cuff that needed to partially cover the right renal artery for an adequate seal. Although there was no filling abnormality of the right renal artery on the completion angiogram, we fully anticipated this renal artery would thrombose, as was demonstrated by postoperative renal duplex scanning.

This patient experienced a myocardial infarction, most likely from pre-existing coronary artery disease plus the sudden pain and hypovolemia associated with the initial contained rupture/syncope event. He did well postoperatively. However, several days after discharge, he returned to the emergency department with shortness of breath and was diagnosed with a pulmonary embolus. He underwent anticoagulation and was discharged several days later. The patient then returned 1 month after discharge with a CT angiogram showing a type II endoleak from the inferior mesenteric artery. This was embolized via a translumbar approach and direct sac puncture. He has done well since with a shrinking aneurysm sac.

Table IV. Summary of key measured variables and outcomes

	Patient A	*Patient B*	*Patient C*	*Patient D*	*Patient E*	*Mean*
Operative blood loss (mL)	350	150	150	150	125	185
Endograft procurement time (h)	4	3	4.5	2	2	3.1
Operating room time (h)	5	4.5	4.5	4.5	3.5	4.4
Creatinine on admission (mg/dL)	1.6	2.4	0.7	0.6	1.1	1.28
Creatinine at discharge (mg/dL)	1.3	1.2	0.6	0.6	1.9	1.12
Days to tolerating by month diet	4	3	1	3	7	3.6
Days to discharge	7	6	2	6	13	6.8
Complications	Diarrhea				Intraoperative myocardial infarct, right renal infarct, PE 2 wk postoperative, endoleak (type II)	

PE, Pulmonary embolus.

The remaining cases were uneventful and had excellent outcomes. Overall survival was 100%. The only patient to have an elevated creatinine level postoperatively was patient E, which was not unexpected after intentional covering of the right renal artery to achieve complete proximal seal. This patient, however, did not require dialysis. Table IV details the key operative and perioperative measured variables and outcomes.

DISCUSSION

The routine use of endovascular technology to treat AAAs is becoming more widespread throughout the world and is performed in about 50% of elective aneurysm repairs.[3] The role of endovascular repair for AAAs with emergency presentations remains experimental. Overall, AAA rupture continues to have an associated overall mortality in excess of 80%.[7] In this article we report on 5 patients with ruptured AAAs in whom open repair would have likely been fatal, yet they were successfully treated with endovascular aneurysm exclusion. With endovascular repair we achieved 100% survival despite associated severe advanced pulmonary and cardiac pre-existing comorbidity. Only 1 patient sustained significant postoperative morbidity but recovered well despite a series of unavoidable complications. Because this patient had an infarct in his myocardium as he arrived at our medical center, it is likely that he would not have survived open repair. The insult of an open repair for a ruptured AAA with its associated cross-clamp on the supraceliac aorta and the bleeding/coagulopathy is usually associated with the disruption of large retroperitoneal hematoma. We found that 50% of our ruptures were treated by endovascular means, which is not the minority, in contrast to what one might have anticipated. This is likely because our total number of ruptured AAA presentations is usually low by virtue of our location with many nearby excellent medical centers. However, this number is skewed toward the higher complexity cases by virtue of our referral patterns.

These 5 patients underwent operation exclusively with commercially available endografts. No grafts were prestocked as part of our operating room inventory. All endografts required sizing and design based on available imaging. In some circumstances (for example, in conversion of an AneuRx bifurcated main trunk to an aortouniiliac design), these devices were used in an off-label fashion. These were unique clinical circumstances that prompted us to push the existing endovascular technology within a zone that we deemed acceptable on the basis of the specific clinical situation and our extensive familiarity with the devices. We hope that future trials will be performed to evaluate endografts specifically designed for aortic rupture. However, the aim of this report is to depict the versatility of our current commercially available devices that can be successfully used in this fashion in some very specific clinical settings. The long-term outcome is not yet known. However, severe pre-existing medical comorbidity was the central indication for us to use an endovascular approach rather than an open approach in these acute presentations. Those same comorbidities would likely make it difficult to obtain long-term data or to ever consider the option of bridging to an open repair.

The anticipated delays one might expect with commercial endograft procurement did not become a logistical problem, although we would acknowledge that waiting for the device could provoke anxiety for all involved. However, if a patient became hemodynamically unstable during the procurement phase, an open repair would have been performed as a last effort. Our mean graft procurement time was 3.1 hours, and our patients' overall procedure-waiting time was estimated to be between 8 and 24 hours including transfer time. Waiting for this time period in a patient with a known AAA rupture might appear unsound. In reference to different clinical scenarios, some authors contend that waiting 1.5 to 2 hours for contained retroperitoneal rupture might improve mortality for open repair by allowing the patient's condition to stabilize and ensuring proper imaging.[8] Although we are well above that limited delay, our good outcomes further extend and support the concept of allowing the patient's condition to equilibrate and generating an adequate treatment algorithm in selected cases. An important concept to implement is to withhold aggressive resuscitation and, in fact, accept mild hypotension (<80-100 mm Hg systolic) that does not result in altered mental status of the patient. This allows for continued hematoma containment and affords additional time for

transport, quick imaging, and prompt endograft procurement.

It is important to recognize that endograft design based on intraoperative arteriography alone is suboptimal, because it is difficult to judge the extent of the aneurysm. Some form of cross-sectional imaging that can delineate the diameters of the proximal and distal fixation points and confirm the infrarenal extent of the aneurysm would be required. However, our experience has shown that it does not have to be a thin-cut contrast-enhanced CT angiogram extending from the hiatus down to the femoral bifurcation. Although such a Stent graft protocol imaging would be ideal, it is not an absolute requirement for emergency endograft design and need not delay prompt repair. As exemplified by this extended case report, the commercially available endografts do confer a significant degree of design flexibility.

Others have adopted protocols for endovascular treatment of ruptured AAAs, reporting improved morbidity and mortality over historical controls.[5,9] The Montefiore group[5] have reported very encouraging results with their homemade Montefiore Endovascular Grafting System (MEGS), which consists of a one-size-fits-all aortouniiliac design supplemented with a femoral-femoral bypass. Because of the in-house endograft availability, their protocol allows for the inclusion of patients with free rupture and hemodynamic instability. In their study, 31 patients presented with AAA rupture, and 25 underwent endovascular graft repair. Six patients with unsuitable anatomy required open repair. Total operative mortality was 9.7% (3 patients). The advantages of the Montefiore model are the immediate availability and one-size-fits-all design.

Another group has reported their experience with the endovascular treatment of ruptured AAAs.[10,11] Although 35% mortality was reported, all patients received detailed contrast-enhanced CT scans regardless of hemodynamic status. Their group used both bifurcated grafts and aortouniiliac devices. This group seemed to be more tolerant of operative delay in favor of adequate imaging and a perfected preoperative Stent graft design. Although such an approach might initially seem unjustifiably risky, in fact, patients with contained retroperitoneal rupture of AAA might have several hours for perioperative planning. A report by Walker et al[12] demonstrated the natural history of ruptured AAA untreated. In this retrospective review of nonoperative cases, they found that patients had a mean life expectancy of 8 hours from admission with ruptured AAA. Therefore, we now view each case individually, balancing the risks of open repair in the setting of significant cardiopulmonary comorbidity versus the risk of any planned delays if an endovascular approach is considered safer for the patient.

Institutions willing to embark on this mode of therapy would need to limit it to hemodynamically stable patients or to establish a method for immediate endograft procurement (ie, stock endografts that would cover a range of fixation diameters). The ability to convert a bifurcated system to an aorto–uni-iliac device (ie, with a proximal extension cuff into the ipsilateral limb) is very important and should be available. Patients with hemodynamic instability would rely on intraoperative arteriography for imaging, decision making, and graft design, unless an expeditious protocol for CT scanning (<15 minutes total) can be implemented. Access to the brachial/axillary artery for supraceliac balloon occlusion can also be a useful adjunct to have available, as has been previously described by the Montefiore group. Because all of our patients were hemodynamically stable, we did not use this technique.

This protocol requires a collaborative effort on the part of emergency department, operating room, radiology personnel, and company representatives for prompt device availability. Advance meetings, discussions, and protocol development within these vital operational components are imperative to ensure timely execution of this treatment algorithm. We found through this experience that a selected stock inventory would serve an expeditious route for treating these patients. Our data would suggest that 2 larger diameter main bodies along with ample accessory components (extensions) and limb diameters would suffice. It is currently difficult to predict whether endografts capable of handling more complex anatomy would have increased the number of patients in this limited series. In addition, without stocking at least the 2 most commonly used sizes of these endografts and a variety of the required ancillary components, it is likely that the reported treatment algorithm would by necessity be relegated to large referral areas in which clinical specialists can "pirate" devices from one hospital to supply another in the setting of an emergency.

Mortality rates for ruptured AAA have remained relatively high despite advances in diagnostic modalities and postoperative care.[13] We believe these 5 cases support the consideration of a novel treatment protocol for ruptured AAA, utilizing the option of commercially available endografts. By demonstrating that patients with extreme comorbidities can survive AAA rupture by using endovascular repair, we propose that other centers that perform high volume endovascular AAA repair can broaden their armamentarium to aid in treatment and potentially improve outcome in this difficult patient population.

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